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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 28

Application Number: 08/962,740
Filing Date: November 03, 1997
Appellant(s): LEVY ET AL.

Amy Hulina
For Appellant

EXAMINER'S ANSWER

This is in response to appellant's brief on appeal filed 6-21-2001.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

(7) *Grouping of Claims*

Appellant's brief includes a statement that the claims do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) *Claims Appealed*

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

5087571	Leder et al	2-1992
5814716	Jallat et al	9-1998

Durbin et al. Cell 84:443-450. 1996

Todaro et al. J. Cell Biology. 17:299-313. 1963.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-5 & 35-37 stand finally under 35 U.S.C. 103(a) as being unpatentable over Durbin et al in view of Jallat et al and Leder et al and also in view of Todaro et al.

Appellant claims an immortalized mammalian cell line homozygous for a *Stat1* null allele.

Durbin teaches the production of a *Stat1* null allele vehicle capable of producing high titers of viruses. The prior art clearly explains that Stat1 (signal transducers and activators of transcription1) is a gene product which interacts with interferon to change the viral tropism of the cell containing the Stat1, i.e. places the cells in an antiviral state. Therefore, a cell or cell line which does not produce the Stat1 product, i.e. a null allele, would be more susceptible to viral infection and replication thus being a good vehicle for viral production. The prior art is remit with attempts to develop such mammalian vehicles which would be preferable to using chicken eggs. The *Stat1* null allele vehicles of Durbin are transgenic mice. Durbin speaks to the development and utility of cell

lines with such an allele (page 443 last 2 paragraphs) but does not teach developing a cell line from the mice. The cell lines referred to are not clearly taught to be immortalized mammalian cell line homozygous for a *Stat1* null allele so there is no anticipation, however t would have been obvious to one of ordinary skill in the art at the time the invention was made to make a cell line from the cells of the transgenic mice of Durbin because Leder and Jallat and also Todaro motivate the artisan to do that and disclose how to make cell lines from transgenic mice. The references (for example Leder Col 9 & Jallet Col 11 & 12) teach that transgenic mice can be made to contain a specific allele and that cells of a variety of types can than be taken from the mouse and said cells will also contain that allele. The cell lines/cultures of Leder and Jallet are "naturally" immortalized as the sequences expressed are oncogenic therefore the references do not teach the immortalization of the cells produced. The immortalization of a cell line produced from a transgenic mouse would have been obvious at the time the invention was made because the immortalization of cells and the desirabilities of immortalization using such tools as SV40 is notoriously old and well known in the art. Non-neoplastic cell lines are of limited use as they will expire even if split and recultured. The desire to immortalize useful cell lines in order to confer extended usefulness is clear motivation to one of ordinary skill in the art and the techniques to do so are notoriously old and well known (this does not appear to be disputed by applicant). The additional descriptive limitations claimed by applicant are fairly broad and appear to be within the ranges of viral susceptibility taught by Durbin and in any

case are inherent properties of the cells of the mouse of Durbin and the obvious cell line developed therefrom. The deposited cell line has not been shown to have any properties beyond the generic claimed cell line and thus the same rejection applies.

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made especially in the absence of evidence to the contrary.

(11) *Response to Argument*

For the above reasons, it is believed that the rejections should be sustained.

The applicant has argued that the prior art does not provide the motivation to make the claim designated cell line, however the prior art does provide a stat null allele animal and the motivation and technique for making cell lines from a transgenic animal. The references render obvious the claimed invention. The motivation to immortalize the cell line is also discussed in the above rejection. Furthermore, even without the implications of viral susceptibility, Durbin and Leder, etc, provide motivation to make immortalized cell lines from the Durbin mouse as an easier vehicle to study the interactions of cytokines and Stat1 proteins. Immortalized cell lines can be readily multiplied and grown to run a plethora of assays much more quickly than the mouse itself.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that

any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

In response to the arguments about claim 35, the relationship between Stat1 and viral tropism/susceptibility is clearly taught in the prior art, thus a Stat1 null allele would inherently (or as taught by Durbin) be more permissive to viral infection.

In response to the arguments about claim 36, the claimed limitation is merely an inherent property of the cell line and thus the cells of the Durbin mouse. The limitation (especially given the broad range disclosed) does not serve to distinguish the cell line from what is obvious in the prior art.

Respectfully submitted,

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LBL
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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER
	28

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Attached is an initialled copy of the 1449 submitted by applicant.

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PTO-90C (Rev.3-98)